

REMARKS

Status of the Claims

Claims 24-59 are currently pending. Claims 1-23 have been canceled without prejudice or disclaimer of the subject matter claimed therein.

Claims 27-29 have been amended to correct an inadvertent typographical error. Representative support for the amendments to claims 27-29 can be found in claims 27-29, respectively, as originally filed.

Oath

An executed oath is attached.

Response to Restriction Requirement

In response to the Restriction Requirement, dated March 17, 2009, Applicants elect with traverse the invention of Group I, claims 24-35 and 54. Although the Office Action indicates on page 2 that Group I is drawn to claims 24-33 and 54, Applicants assume that this is an inadvertent typographical error and that Group I includes claims 24-35 and 54 because page 6 of the Office Action states that claims 34 and 35 are included in Group I.

The Office Action has also requested an election of species. Applicants elect with traverse the following species:

1. a lipid for cationic amphiphile in claim 26;
2. a quaternary ammonium group in claims 27 and 29;
3. a polyelectrolyte for cationic polymer in claim 30;
4. a lipid for anionic/neutral amphiphile in claim 32;
5. a phospholipid for lipid in claim 34.

Claims 24-32, 34, and 54 read on the elected species. Claims 24, 25, 31, and 54 are generic as to the claims of Group I.

Applicants respectfully traverse the Restriction Requirement. The Office Action alleges that the inventions of Groups I-IV are not linked so as to form a single inventive concept because it would be obvious to combine the teachings of Ray *et al.* (Ray) and Yang *et al.* (Yang) to obtain the claimed invention of Group I. Applicants respectfully point out that as is

acknowledged by the Office Action, Ray does not teach the claimed composition and that the combination of Yang and Ray do not render the claimed invention obvious. Yang teaches away from the claimed invention because Yang teaches that the carboxylate form of camptothecin has low biological activity and severe toxicity (see page 751, right column, first full paragraph). Moreover, it is known that the opening of the lactone ring of camptothecin at physiological condition to form the carboxylate species results in loss of *in vitro* activity and diminished *in vivo* anticancer activity (see page 751, right column, first full paragraph). Yang recommends the use of camptothecin in its lactone form (non-hydrolyzed form) instead of the carboxylate form, as a drug for oral administration because Yang found that camptothecin loaded solid lipid particles (CA-SLN) is a very promising drug delivery system (see page 756, right column, first section). Camptothecin delivered in the form of CA-SLN is prevented from hydrolyzing into its carboxylate form. Accordingly, the combination of the teachings of Yang and Ray do not render the claimed invention obvious.

The special technical feature of the inventions of Groups I-IV is a composition comprising the carboxylate form of a camptothecin drug. Since the cited references do not render the claimed invention obvious and the claimed inventions share a special technical feature, the inventions of Groups I-IV are linked so as to form a single inventive concept. Applicants respectfully request that the inventions of Groups I-IV be searched and examined together in this application.

Moreover, the invention of Group II is drawn to a colloidal nanoaggregate comprising the composition of the invention of Group I, and the inventions of Groups III and IV are directed to methods of using the inventions of Groups I and II. Thus, it would not require undue burden to search and examine all the inventions in this application.

Further, Applicants respectfully point out that MPEP 821.04(b) requires that once a product claim is found allowable, withdrawn method claims which depend from or otherwise include all the limitations of the allowable product claim must be rejoined. Thus, once a claim directed to a product (claims 24-50 and 54) is found allowable, withdrawn method claims (51-53 and 55-59) which depend from or otherwise include all the limitations of the allowed claim must be rejoined.

Regarding the species election, it is Applicants' understanding that the Examiner intends

to begin by searching the elected species and will continue searching until art is found or until a generic claim is found allowable. Applicants also point out that when a generic claim is found to be allowable, the withdrawn claims which depend from or include the limitations of the allowed claim must be rejoined and fully examined for patentability. MPEP 809.

Conclusion

The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicants respectfully request entry of the amendments, reconsideration, and the timely allowance of the pending claims. A favorable action is awaited. Should an interview be helpful to further prosecution of this application, the Examiner is invited to telephone the undersigned.

If there are any additional fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,
Morgan, Lewis & Bockius LLP

/Sally Teng/

Date: April 17, 2009
Morgan, Lewis & Bockius LLP
Customer No. 09629
1111 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
Tel: 202-739-3000
Fax: 202-739-5734

Sally P. Teng
Registration No. 45,397